Study Title: Co-designing an automated prompt and personalised consultation print-out

for children with respiratory tract infections in general practice

**Ethics approval reference:** R71870/RE001

**Principal Investigator:** Dr Oliver Van Hecke , University of Oxford

**PARTICIPANT INFORMATION SHEET**

***Parents and carers of preschool children***

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

**What is the purpose of this research?**

The main aim of the research is to invite parents and carers of preschool children to help us design a computer screen prompt, which will automatically calculate a child’s antibiotic history during appointments at the GP.

We are interested in talking to parents and carers during group workshops about how they perceive this computer prompt, and a personalised consultation print-out summarising their child’s consultation at the GP.

This research will tell us how best to do this and what parents think about this computer screen prompt and personalised print-out. This will make sure that it is acceptable for parents and healthcare professionals in the GP surgery.

**Why the interest in a child’s antibiotic history?**

Recent research from over 250,000 UK children has found that children who had taken two or more antibiotic courses in the last year for “respiratory tract infections” (RTIs) - the typical coughs, sore throats, or earaches which children get - had around a 30% greater chance of not responding to treatment for future RTIs compared to children who had not taken any antibiotics. This ‘antibiotic history’ is currently not routinely used during GP appointments.

**Why have I been invited?**

For each workshop, we are inviting around 4 to 8 parents or carers of preschool children (6 months to 5 years) with a recent ‘respiratory tract infection’ - your typical cough, sore throat or earache within the previous 3 months). You do not need to have consulted a healthcare professional or been prescribed an antibiotic for your child.

**What do I have to do?**

During the workshop, you will be asked about your views of using a child’s antibiotic history in consultations, and for feedback on the design and acceptability of a computer screen prompt and a personalised printout that GPs and nurses will aim to use during their consultations with children with respiratory tract infections.

The workshop will be arranged at a time to suit you at the Nuffield Department of Primary Care Health Sciences in Oxford or online (on Microsoft Teams) and will last between 90-120 minutes.

Before starting the workshop, you will be asked to each given verbal consent to confirm that you fully understand what taking part in the study will involve and that your questions about the research have been answered. A copy of the consent form will be emailed to you for your records. The workshop will be audio-recorded with your permission to make an accurate record of what is said. As this is a group workshop, participants who do not wish to be recorded will not be able to participate.

**Do I have to take part?**

No, your participation in the group workshop is voluntary. You can ask questions about the study before deciding whether to participate. You will be given as much time as you need to decide whether to take part. You may also withdraw at any time without providing a reason. If you do wish to withdraw after the start of the workshop, any data collected during the group workshops will not be able to be deleted.

**What are the advantages and disadvantages of taking part?**

There are no direct advantages or disadvantages to you. We hope the information gained from this study will be used to improve the design of the computer screen prompt and personalised print-out so that it can be used effectively during GP consultations.

**Will my taking part in the study remain confidential?**

The research data will be stored confidentially on University of Oxford premises and university computer networks.

The audio recording of your interview will be labelled with an anonymous number and stored in a study folder that can only be accessed by the research team on the University of Oxford IT network. At this point, the recording will still be identifiable via your voice. The recording will be sent securely to an independent transcription company who will type up the recording. The company will have been assessed and approved for data security by the University of Oxford. Once the recording has been transcribed, this written record (transcript) will be checked for accuracy and the audio-recording will be deleted at the end of the study. The transcript of the audio recording will be de-identified, which means that it will not include any names or other defining details that can identify you.

So that we can speak to a wide range of parents, we will collect specific demographic details (your age, number of children in family, age and ethnicity of child) prior to the workshop. We will also collect personal data will include your name, contact details, the written record of your verbal consent taken in your workshop. All paper copies of data will be securely stored within a lockable filing cabinet, in an access-controlled room and will be destroyed at ten years after the end of the study. Other personal data will be stored securely in password protected files on secure computers and on the University of Oxford IT network; only the research team will be able to access them.

The transcript of the workshop will be stored in an online data repository available for future research and kept for 10 years following the end of the study. The findings from this study will be used in research reports but no names will be included in the report so any quotes from the interview will be anonymous. We will ask all participants for their permission to use direct quotes. All quotes will be de-identified. We will retain a list of participant names and details against participant numbers. This will be stored on University of Oxford computers as password protected files until the end of the study. Responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Key policies and documents relating to information/data security include:

Data Protection Act 2018

Nuffield Department of Primary Care Health Sciences Information Security policies

University Data Protection policy: <https://compliance.admin.ox.ac.uk/data-protection-policy>

The University of Oxford is the data controller with respect to your personal data, and as such will determine how your personal data is used in the study. The University will process your personal data for the purpose of the research outlined above. Research is a task that is performed in the public interest. Further information about your rights with respect to your personal data is available from <http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/>.

**What happens if something goes wrong?**

If you have a concern about any aspect of this study, please contact Dr Oliver Van Hecke, 01865 617 94, oliver.vanhecke@phc.ox.ac.uk, and I will do my best to answer your query. I will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Medical Sciences Interdivisional Research Ethics Committee at the University of Oxford who will seek to resolve the matter as soon as possible: Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD

**What will happen to the results of the research study?**

The results will be published in a scientific journal and the findings will inform a future trial aimed at testing whether the use of this computer screen prompt can effectively reduce the number of antibiotic prescriptions prescribed for children with respiratory tract infections in general practice. A summary of the findings will be sent to all participants who would like to see the results and the full report can be made available on request.

**Will I be reimbursed for any expenses?**

Taking part in this research is voluntary. If you complete a workshop with a member of the research team, you will receive a £20 gift voucher as a token of our appreciation. Reasonable travel costs will be reimbursed.

**Who is organising and funding this study and who has reviewed it?**

This research is being organised by the Department of Primary Care Health Sciences, at the University of Oxford and is being funded by an Academy of Medical Sciences Starter Grant for Clinical Lecturers.

**Who has reviewed this study?**

This study has received ethics approval from a subcommittee of the University of Oxford Central University Research Ethics Committee (Ethics reference: R71870/RE001).

**Where can I get more information?**

If you would like to take part in the study, or if you have any further questions, please do not hesitate to get in touch with Dr Oliver van Hecke using the contact details below.

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